

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PAIK, Nam-Hoon

14th Fl., KTB Network Bldg., 826-14, Yeoksam-dong,
Kangnam-ku Seoul 135-769 Republic of Korea

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **14 DECEMBER 2004 (14.12.2004)**

Applicant's or agent's file reference
227

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2004/002590

International filing date (day/month/year)

11 OCTOBER 2004 (11.10.2004)

Priority date(day/month/year)

10 OCTOBER 2003 (10.10.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 31/56

Applicant

SK CHEMICALS, CO., LTD. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

LEE, Mi Jeong

Telephone No. 82-42-481-5601



Best Available Copy

Express Mail No. EV746682335US

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2004/002590

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Best Available Copy

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2004/002590

Best Available Copy

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1 - 5	NO
Inventive step (IS)	Claims		YES
	Claims	1 - 5	NO
Industrial applicability (IA)	Claims	1 - 5	YES
	Claims		NO

2. Citations and explanations :

The following documents are referred to in this report:

D1: Mol. Cells Vol.11(2), pp.137-143 (30 Apr. 2001)

D2: Mol. Cells Vol.13(1), pp.5-11 (28 Feb. 2002)

D3: KR 2003-0042123 (28 May 2003)

1. Novelty and Inventive Step

Claims 1-4 of the present invention relate to a pharmaceutical composition comprising a triterpene compound of formula 1 such as oleanolic acid, hederagenin, and ursolic acid for the improvement of brain function and for the prevention and treatment of mild cognitive impairment or Alzheimer's disease.

Claim 5 of the present invention relates to a composition of health food for the improvement of brain function comprising a triterpene compound of formula 1.

D1 discloses that ursolic acid is an acetylcholinesterase(AChE) inhibitor and that AChE inhibitors are approved for the treatment of Alzheimer's disease.

D2 discloses that an amyloid beta protein increases free radical production and lipid peroxidation in PC12 nerve cells, leading to apoptosis and cell death and pretreatment with ursolic acid and vitamin E inhibits the amyloid beta protein-induced neurotoxic effect.

D3 discloses that triterpene compounds such as oleanolic acid are effective in treatment of chronic diseases such as Parkinson's disease and Alzheimer's disease by inducing apoptosis, and the said triperpene compouds are useful in the pharmaceutical or health food industry.

As mentioned before, the medical use of oleanolic acid and ursolic acid for the improvement of brain function and for treatment of Alzheimer's disease claimed in claims 1-4 of the present invention is already disclosed in D1-D3.

A composition of health food for the improvement of brain function comprising oleanolic acid claimed in claim 5 of the present invention is also disclosed in D3.

Thus, the novelty of claims 1-4 of the present invention can be negated by D1, D2, or D3 and the novelty of claim 5 can be negated by D3 [Article 33(2) PCT].

(Continued on Supplemental Sheet.)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2004/002590

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of :

Box V.

Since the novelty of claims 1-5 cannot be acknowledged over D1-D3, the inventive step of claims 1-5 cannot be acknowledged over D1-D3, either [Article 33(3) PCT].

2. Industrial Applicability

The subject-matter of claims 1-5 appears to be industrially applicable [Article 33(4) PCT].

Best Available Copy